

2

Vaccine Management

The high cost and perishable nature of vaccine products obligates state and local immunization programs to maintain efficient vaccine distribution systems and closely monitor vaccine handling and storage practices to minimize vaccine wastage and loss. Vaccine potency may be compromised through poor vaccine handling practices. As a result, immunization programs and their distribution

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contractors that order, store and distribute vaccines to providers have a critical responsibility to safeguard the products within their systems. They must have the proper equipment, materials, and expertise to correctly handle, store, package, and ship vaccines to providers. An efficient vaccine distribution system demands user-friendly ordering procedures, appropriate packing and shipping methods, a distribution arrangement that minimizes cost and vaccine

handling, and documented accountability of every dose purchased.

Immunization programs also have a prime responsibility to assure appropriate use of public vaccine and to vigorously enforce measures to prevent fraud and abuse of public vaccine at the provider level. This is accomplished through provider education and quality assurance aspects of vaccine ordering, storage, handling, safe administration and wastage within the office or clinic.

For additional details on VFC program requirements, please refer to the current VFC Program Operations Guide published by CDC. Also see Chapter 4. Provider Quality Assurance.

ACTIVITY AREAS

2.1 Vaccine Ordering, Distribution and Storage Systems

2.2 Vaccine Accountability (Provider Level)

References:

- 2002 VFC Program Operations Guide (CDC)
- *Vaccine Management: Recommendations for Handling and Storage of Selected Biologicals*, (CDC) (CD Rom 2003 Immunization Works)
- *Guidelines for Vaccine Packing and Shipping* (CDC)
- ACIP Recommendations: General Immunization, Adolescent Immunization, Adult Immunization and Vaccine-Specific Recommendations, (CDC) (CD Rom 2003 Immunization Works)
- Toolkit for Evaluating Immunization Clinic Attendance (available from Program Support Branch, NIP, (404) 639-8222. DTQ1@CDC.GOV)

2.1 VACCINE ORDERING, DISTRIBUTION and STORAGE SYSTEMS

ACTIVITIES to maintain adequate inventories in the public vaccine distribution “pipeline.”

✓ **2.1.1** Maintain an efficient system to distribute public vaccine. The system can be managed directly by the program or through contracts with specialized private pharmaceutical distributors or through a combination of both. See 2.1.0 *CHARACTERISTICS of an efficient vaccine distribution system.*

✓ **2.1.2** Order vaccine in accordance with an annual vaccine spending plan that outlines population-based vaccine needs, funding sources and purchase schedules for each antigen. See *Chapter 1.2 Vaccine Financing.*

2.1.0 CHARACTERISTICS of an efficient vaccine distribution system

- Efficient (minimal distribution levels)
- Minimizes vaccine handling
- Low cost per dose shipped
- Secure (maintains cold chain)
- Reliable

ACTIVITIES to assure vaccines are delivered to providers in a timely manner:

✓ **2.1.3** Process provider vaccine orders in a timely, efficient and accurate manner.

Performance Measure: Number or percent [improvement] of providers responding positively to provider survey questions concerning timeliness, efficiency and accuracy of the processing of their vaccine orders

Target: Set by individual program

✓ **2.1.4** Supply all ACIP-recommended vaccines to VFC providers in accordance with current ☞ VFC-ACIP resolutions.

✓ **2.1.5** Supply all ACIP-recommended vaccines available to all public providers, including STD clinics, which serve under-insured children, adolescents, and/or high risk adults.

ACTIVITIES to assure that vaccines remain effective (potent):

✓ **2.1.6** Develop, regularly review, and, as necessary, update written standard operating procedures (SOPs) for vaccine ordering, receiving, storage, handling, shipping, tracking and disposal. SOPs should include contingencies for power outages, natural disasters and other emergencies that involve the physical relocation of vaccines.

✓ **2.1.7** Ensure that vaccines within the program's distribution system are handled, stored and shipped in accordance with CDC Guidelines. See *Vaccine Management: Recommendations for Handling and Storage of Selected Biologicals*, (CDC) (CD Rom 2003 Immunization Works). Due to local temperature extremes, some states will find these recommendations to be inadequate. Packing and shipping procedures for these states should be documented and justified. Additional cost may also be justified.

✓ **2.1.8** Safeguard public vaccines by providing facility security such as refrigerator locks, temperature and burglar alarms, and restricted access to vaccine storage and handling areas. For large vaccine depots, back-up generators should be installed and regularly tested.

✓ **2.1.9** Rotate vaccine inventories to ensure that vaccine received first is shipped out first.

2.1.10 Maintain a secure quarantine area for wasted vaccines.

✓ **2.1.11** Provide training on appropriate vaccine ordering, handling, storage, shipping and accounting to all staff and their back-ups, for both program and/or contractor employees involved in the public vaccine distribution system. Training should be prioritized based on findings of quality assurance reviews of vaccine ordering, storage, handling and accounting practices within the state/local public vaccine distribution system.

Performance Measure: *Number of vaccine management trainings conducted*
Target: *Set by individual program*

2.1.12 Request VFC providers to notify the program of any vaccine doses which will expire before they will be able to administer it. Whenever the cold chain can be assured, redistribute short-dated vaccines to high volume providers who are able to administer it before it expires.

2.2 VACCINE ACCOUNTABILITY (Provider Level)

ACTIVITIES to ensure the appropriate use of vaccine purchased with VFC and other public funds at the provider level and to prevent fraudulent use of vaccines purchased with public funds:

For more activities related to vaccine accountability, refer to Chapter 4. Provider Quality Assurance.

- ✓ **2.2.1** Use VACMAN software application for processing vaccine orders, distributing vaccines and other vaccine management activities.
- ✓ **2.2.2** Immediately report to CDC instances of possible fraudulent use of vaccine purchased with federal funds. Work closely with Medicaid and other appropriate state legal authorities in VFC fraud investigations and complete and submit to your NIP, VFC Consultant a preliminary investigation within five working days of the initial report.
- ✓ **2.2.3** Require providers to update and submit updated Provider Profiles at least
☞ annually. The name, medical license number and Medicaid provider number (if applicable) of each provider practicing at each enrolled site should be documented. VFC site documentation and VFC Provider Profiles should be maintained for at least three years.

Performance Measure: *Percent of provider sites enrolled in the VFC Program that have completed a Provider Profile in the last year*

TARGET: 100%

- ✓ **2.2.4** Ensure that VFC providers accurately identify the number of VFC-eligible and
☞ non-VFC-eligible children served by comparing Provider Profiles with information obtained during on-site visits. *See Chapter 4.2 Provider Site Visits for additional details.*
- ✓ **2.2.5** Review and approve provider vaccine orders, ensuring that the orders reflect each provider's vaccine needs and are consistent with the **number** of VFC-eligible children reported in the most recent Provider Profile.

Performance Measure: *Number of doses of VFC and non-VFC vaccine shipped to each provider annually*

Target: *Concordance between the amount of vaccine shipped to each provider and the amounts reflected in the Provider's Profile*

✓ **2.2.6** Monitor providers' use of public vaccine through bench marking, doses administered reports and/or other techniques; evaluate individual provider usage by comparing with prior usage.

2.2.7 Survey providers enrolled in the VFC program at least biennially to determine their satisfaction with the program.

ACTIVITIES to minimize and document vaccine loss and wastage at the provider level:

✓ **2.2.8** Document expired and wasted doses of public vaccine by developing and implementing written procedures for providers to report and responds to all losses resulting from vaccine expiration, wastage, and compromised cold chain.

Performance Measure: *Number of doses [and dollar value] of vaccine lost (expired and wasted)*

Target: *Concordance between doses reported lost with an independent calculation of doses lost using inventory and doses administered reports. Total doses lost, wasted, or unaccounted for should not exceed 5%.*